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09/614,790	07/12/2000	Sharon F. Kleyne	HME/7982.001	2570

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EXAMINER

WILLIS, MICHAEL A

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 14

Application Number: 09/614,790

Filing Date: July 12, 2000

Appellant(s): KLEYNE, SHARON F.

MAILED

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Howard Eisenberg
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 30 September 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief. The brief identifies the real party in interest in the appeal as "the party named in the caption of this brief". This is understood by the examiner as Sharon F. Kleyne.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. The brief states that "there are no such appeals or interferences".

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims grouped as 75-77, 78, 79-81, and 82 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8). Appellant states that "Reasons for the above grouping of the claims is provided in the Arguments under 37 CFR §1.192(c)(8) that follows". However, the appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because while reasons for claims 79-82 standing or falling together are given, no reasons are given for why claim 78 should stand or fall by itself. Nor is a reason given for why claim 82 should stand or fall by itself.

(8) ClaimsAppealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

WO 97/23177	Embleton et al.	07-1997
US 5,997,518	Laibovitz et al.	12-1999

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 75-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Embleton et al (WO 97/23177) in view of Laibovitz et al (US Pat. 5,997,518). This rejection is set forth in prior Office Action, Paper No. 11.

(11) *Response to Argument*

With respect to claims 75-82, appellant argues that the examiner failed to consider the preamble as a limitation, and further that the examiner has improperly disregarded the Declaration of Dr. Rachel Garrett.

The preamble of claim 75 recites "A method for moisturizing the eye". The preamble is considered as a limitation. Embleton teaches the desirability of delivering a controlled, small amount of fluid to the eye. The delivery of too much fluid to the eye will result in flooding the eye with runoff onto the cheek. Embleton teaches that "an argument could be made for the use of smaller instilled volumes of eye drops than are normally delivered by most commercial ophthalmic droppers. Drainage loss would be minimized; contact time increased and hence the potential exists for improved drug activity" (Embleton, page 2, lines 15-22). The limitation of a method for moisturizing the eye is considered within the teachings of Embleton's ophthalmic treatments, particularly as Embleton later recites "Ophthalmic treatment liquids that may be used with the invention may be aqueous or non-aqueous liquids, optionally containing a therapeutic compound or compounds such as:6) Artificial tear/dry eye therapies, comfort drops,

irrigation fluids, etc., physiological saline, water, or oils" (Embleton, page 12, line 6 through page 13, line 12). Artificial tear/dry eye therapies are considered by the Examiner to render obvious a method for moisturizing the eye.

With respect to the Declaration of Dr. Rachel Garrett, appellant cites paragraph 4 of her Declaration: "Artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects." Appellant argues that the evidence for dry eye therapies consisting of water supplied by the Examiner is not pertinent to the issue addressed by the Declaration. Appellant argues that because Ogura (US Pat. 5,307,095) and Scheiner (US Pat. 5,627,611) use water as a dry eye therapy in a continuous rather than episodic means of administration, therefore the references are not pertinent to the understanding of the terms used by Embleton. It is the position of the examiner that the time-course of administration is not pertinent to the question of whether or not "water" is known in the art as an agent for dry eye therapy. While the Examiner cannot refute the Declaration of Dr. Rachel Garrett with respect to commercially available artificial teardrops, comfort drops or irrigation fluids, the characterization of dry eye therapies as necessarily requiring components in addition to water is not convincing. Clearly, Ogura and Scheiner demonstrate that "water" is known in the art as an agent for dry eye therapy. Furthermore, it is noted that the claims are drawn to methods comprising administering fluid "consisting essentially of" water. Even if appellant's characterization of dry eye therapies is accepted, the MPEP clearly states that absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be

construed as equivalent to "comprising" (see MPEP 2111.03). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of" applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention (see MPEP 2111.03).

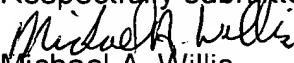
With respect to claims 79-82, appellant argues that the examiner has improperly rejected appellant's definition of the term "mist". Appellant argues that the term "mist" is defined by appellant in a way that is entirely consistent with its accepted usage and that the Examiner is attempting to broaden the term to include forms of liquid which are other than mists. However, the examiner fails to see how Embleton's use of "jet or stream of droplets" is inconsistent with appellant's use of "mist", particularly where appellant's own definition includes "a cloud of particles resembling this: *She sprayed a mist of perfume onto her handkerchief*" (emphasis in the original). Appellant argues that in contrast to the teachings of Embleton which suggest that the therapeutic fluid can be targeted at a chosen site in an eye, a mist cannot be directed or targeted at a chosen site in an eye. The examiner fails to see how the appellant reaches this conclusion based on a definition including the phrase "She sprayed a mist of perfume onto her handkerchief". Embleton's use of "jet or stream of droplets" is consistent with a mist such as that sprayed from a perfume bottle onto a handkerchief.

Appellant further argues that the references are improperly combined where Embleton teaches a "jet or stream of droplets" for delivery of small volumes of liquid,

and Laibovitz teaches an apparatus for delivering a small volume of liquid in the form of a mist. As stated above, the "jet or stream of droplets" is understood by the examiner as consistent with Appellant's definition of mist as a cloud of liquid particles such as that sprayed forth from the nozzle of a perfume bottle at the desired target of a handkerchief. Embleton cannot be characterized as teaching away from the use of a mist, when the "jet or stream of droplets" taught by Embleton is consistent with a cloud of liquid particles such as that sprayed forth from the nozzle of a perfume bottle at a particular target such as a handkerchief. Appellant's argument regarding improper combination of references is even less convincing in view of appellant's admission that the disclosure of Laibovitz regarding droplet size "is compatible both with a mist and with a jet or stream of droplets" (see Appellant's brief, page 21, lines 15-16).

Appellant further argues that, despite the fact that Laibovitz teaches "Of particular interest is the ability of the system to deliver small volumes...of a liquid as droplets. The droplets are much smaller in size than a normal drop of the liquid. The size of the drop may be generally the size such as is found in an aerosol or mist which may be in the micron range" (see col. 3, lines 20-25), one of ordinary skill in the art cannot say that Laibovitz discloses the administration of a mist. Appellant's argument is not convincing. It is the position of the examiner that a teaching of the administration of liquid droplets such as those found in a mist is to be understood by one of ordinary skill in the art as a teaching of the administration of a mist.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Michael A. Willis
Examiner
Art Unit 1617

maw
October 24, 2002

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